UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL.,

Plaintiffs,

v. **No. 4:24-cv-0953-P**

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Defendants.

OPINION & ORDER

Before the Court is Plaintiffs Outsourcing Facilities Association's and North American Custom Laboratories LLC Partners' (collectively "Plaintiffs") Motion for Preliminary Injunction and Stay (ECF No. 64). Having considered the briefing and applicable legal authorities, the Court will **DENY** Plaintiffs' Motion.

BACKGROUND

A. Regulatory Background

The Federal Food, Drug, and Cosmetic Act ("FDCA") generally prohibits the introduction of a "new drug" into interstate commerce without the United States Food and Drug Administration's (the "FDA") approval. 21 U.S.C. § 355(a). To obtain FDA approval, a manufacturer generally must submit a new drug application ("NDA"). *Id.* § 355(b)(1). The FDA adjudicates such applications and approves them only if it finds, based on the evidence before it, that the drug is safe and effective for its intended use under the conditions of use described in the drug's labeling. *Id.* § 355(c)(1)(A), (d). Once an NDA is approved, facilities producing the new drug generally must comply with "current good manufacturing practice[s]" ("cGMP"), which "assure[s] that such drug meets the requirements of this chapter as to safety and has the identity

and strength, and meets the quality and purity characteristics, which it purports . . . to possess." *Id.* § 351(a)(2)(B); *see* 21 C.F.R. Pts. 210, 211.

In order to protect patients and ensure efficacy, the FDA's approval process is demanding. Each drug seeking the FDA's approval must be evaluated through three increasingly complex phases of studies, typically culminating in double-blind, multi-center, placebo-controlled clinical trials. The sponsor must detail every ingredient and component in its application to the FDA. 21 U.S.C. § 355(b)(1)(A)(i)–(viii). The FDA conducts inspections to ensure compliance with cGMP, *id.* § 351(a)(2)(B), reviews the drug's labeling to ensure appropriate disclosure of side effects, warnings and contraindications, *id.* § 352(f)(1)–(2), and monitors advertising and promotion to ensure it is not misleading, *id.* §§ 321(n), 352(a)(1), 352(n). The FDA also requires manufacturers to track and trace each finished product, *id.* § 360eee-1, to promptly report all adverse events, *id.* § 355(k), and to conduct further post-approval studies, *id.* § 355(o). Because of the FDA's rigorous requirements, "[o]n average, it takes 10-15 years and costs $2.6 billion to develop one new medicine."[1]

Despite the difficulties in getting new drugs approved, companies regularly invest in the research and development of new drugs due to the incentives created by Congress. Relevant here, new chemical entity exclusivity is earned whenever the FDA approves a new medicine for the first time. 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii). This statutory exclusivity means that for five years the FDA is prohibited from approving another manufacturer's application for any drug using the same active moiety. *Id.*

In addition to subjecting all new drugs to the NDA process, the FDCA regulates when drug compounding is permitted. Drug compounding is "a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication," is "a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools." *Thompson v. W. States*

[1]PhRMA, *Research and Development Policy Framework* (Sept. 2024), https://tinyurl.com/5eecdtm9.

Med. Ctr., 535 U.S. 357, 360–61 (2002) (internal citation omitted). For example, the FDCA allows licensed pharmacists and physicians to compound a version of an FDA-approved product to address patient-specific needs, such as creating a liquid version of a medication for a patient who has trouble swallowing solids. *See* 21 U.S.C. § 353a.

Compounding pharmacies and physicians whose drugs meet the conditions of 21 U.S.C. § 353a (hereinafter "503A compounders") are not required, *inter alia*, to follow cGMP. On the other hand, outsourcing facilities (hereinafter "503B compounders") are subject to cGMP, registration, and product reporting requirements. *Id.* § 353b. Regardless of who produces them, compounded drugs are not subject to the safety requirements that apply to FDA-approved drugs because they do not undergo the FDA's premarket review for safety, effectiveness, and quality. Due to this reduced oversight, Congress has generally prohibited compounders from producing products that "are essentially copies of a commercially approved drug." *Id.* §§ 353a(b)(1)(D); 353b(a)(2)(A)(ii). Nonetheless, this prohibition is temporarily lifted when a drug is placed on the "shortage list."

The FDCA defines "shortage" as "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." *Id.* § 356c. Further, the FDCA requires the FDA to "maintain an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." *Id.* § 356e(a). For every drug the FDA adds to its shortage list under this provision, it is required to identify "[t]he name of the drug in shortage," "[t]he name of each manufacturer of such drug," "[t]he reason for the shortage" from an enumerated list of seven categories, and "[t]he estimated duration of the shortage as determined by the [FDA]." *Id.* § 356e(b)(1)–(4). When a drug is placed on the FDA's shortage list, Congress permits 503A compounders to compound copies of the drug and 503B compounders to compound from that drug's active ingredient—which is otherwise prohibited—including by compounding drugs that are "essentially a copy" of an approved drug. *See Id.* §§ 353b(a)(2)(A)(ii), (a)(5), (d)(2)(A). Because, as discussed above, compounders are subject to less oversight

than drug manufactures, the FDCA permits this type of compounding only while a shortage persists.

B. Factual and Procedural Background

The drugs relevant to this case are Mounjaro® and Zepbound® (collectively the "Lilly Drugs"). The FDA approved the Lilly Drugs pursuant to Intervener Eli Lilly and Company's ("Lilly") marketing applications in 2022 and 2023, respectively. The Lilly Drugs contain a complex molecule called tirzepatide, which targets hormone receptors (called GIP and GLP-1). The FDA approved Mounjaro® for adults with type 2 diabetes mellitus seeking to improve their glycemic control. And the FDA approved Zepbound® for adults with obesity, weight-related medical problems, and moderate to severe obstructive sleep apnea. Given the groundbreaking nature of these drugs, Lilly experienced unprecedented demand, which it was unable to meet. As a result, the FDA placed the Lilly Drugs on its drug shortage list.

The Lilly Drugs remain protected by statutory exclusivity, meaning that the FDA is prohibited by law from accepting an NDA or abbreviated NDA for any tirzepatide product from any company other than Lilly until June 2027. *See* 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2), (b)(3). However, as discussed above, this exclusivity is suspended while the drugs remain on the FDA's shortage list. Thus, until the drugs are removed from the shortage list, compounders can legally produce similar products to help satisfy the demand not filled by Lilly.

In an effort to regain its exclusive right to produce and sell tirzepatide products—by having the Lilly Drugs removed from the FDA's shortage list—Lilly spent roughly $23 billion to build, expand, acquire, or obtain internal and external manufacturing facilities in the United States and Europe. Additionally, in August 2024, Lilly obtained supplemental FDA approvals authorizing the sale of the Lilly Drugs in single-use vials—on top of addition to the already approved auto-injector devices—allowing Lilly to more readily supply doses of the drugs. As a result of Lilly's efforts, the FDA updated the shortage list to reflect that "[a]ll doses of Mounjaro® and Zepbound® [were] available." Two

months after that announcement, on October 2, 2024, the FDA announced that the tirzepatide shortage was over and that the Lilly Drugs would be removed from the shortage list.

Five days later, on October 7, 2024, Plaintiffs filed this lawsuit. On October 11, 2024, the FDA filed an unopposed motion to remand and stay the case so that the FDA could "reevaluate the decision at issue in this case." The Court granted the motion, and the FDA reconsidered its decision. On December 19, 2024, the FDA issued a "Delisting Action" reaffirming its decision to remove the Lilly Drugs from the shortage list. The Delisting Action was memorialized in two documents. The first, titled the "Decision," presented the evidence considered by the FDA and its reasoning. The second, titled the "Order," summarized the FDA's rationale and provided that the FDA would exercise its enforcement discretion to delay the enforcement of its decision.

Thereafter, on January 1, 2025, Lilly filed its Motion to Intervene, which the Court granted on January 6, 2025. On January 2, 2025, Plaintiffs and the FDA filed a Joint Motion to Reopen the Case and Enter Scheduling Order. After holding a hearing on January 14, 2024, the Court reopened the case and set a briefing schedule for the present Motion. The Parties, and *Amici Curiae*, have filed their respective briefs and the Motion is ripe for determination.

LEGAL STANDARD

A preliminary injunction is an "extraordinary remedy" and will be granted only if the movants carry their burden on four requirements. *Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008). The movants must show: "(1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) the threatened injury to the movant outweighs the threatened harm to the party sought to be enjoined; and (4) granting the injunctive relief will not disserve the public interest." *City of Dall. v. Delta Air Lines, Inc.*, 847 F.3d 279, 285 (5th Cir. 2017) (cleaned up). "The decision to grant or deny a preliminary injunction is discretionary with the district court." *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ANALYSIS

The Court begins with Plaintiffs' likelihood of success on the merits for their claims against Defendants. For the reasons stated *infra*, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of their claims, which is the most important (and usually decisive) factor. *See Tesfamichael v. Gonzales*, 411 F.3d 169, 176 (5th Cir. 2005); *Baird v. Bonta*, 81 F.4th 1036, 1041 (9th Cir. 2023). While the Court's analysis could end there, in an abundance of caution, the Court will briefly address the other preliminary injunction elements.

A. Likelihood of Success on the Merits

Plaintiffs' Amended Complaint raises six claims for why the FDA's Delisting Action should be set aside. *See generally* ECF No. 68. Plaintiffs, in their Motion for Preliminary Injunction, do not address their fifth cause of action—unlawful interpretation of the statute under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). *Id.* at 22. Thus, because Plaintiffs did not raise it as a basis for injunctive relief, the Court's analysis focuses on the other five claims, which are addressed in Plaintiffs' Motion.

Those claims are: (1) rulemaking without conducting notice and comment; (2) failure to consider the statutory factors; (3) facially contradictory findings that undermine the basis of the agency action; (4) failure to consider countervailing evidence; and (5) failure to publish a rule in the federal registry. ECF No. 68 at 17–24. Because claims one and five are both predicated on the Delisting Action being a rule, the Court considers them together. Similarly, Plaintiffs' remaining three claims are considered together as they all involve whether the Delisting Action was arbitrary and capricious.

1. Notice-and-Comment and Failure to Publish Claims

For the Court to determine Plaintiffs' likelihood of success on the merits on their notice-and-comment and failure to publish claims, the Court must first determine how to categorize the Delisting Action. The Parties do not dispute that the Delisting Action is a final agency action subject to judicial review under the Administrative Procedures Act

("APA"). However, the Parties do dispute how to classify the FDA's Delisting Action. Plaintiffs assert that the Delisting Action is a substantive rule. ECF No. 64 at 8. On the other hand, Lilly and the FDA (collectively the "FDA Defendants") claim that the Delisting Action is an informal adjudication. ECF Nos. 83 at 16; 90 at 17–18. If the Delisting Action is a substantive rule, as Plaintiffs urge, then then the FDA was required to comply with the APA's stringent notice-and-comment requirements and that process is reviewed under the arbitrary and capricious standard. But if the Delisting Action is an informal adjudication, as the FDA Defendants urge, then the Court simply reviews the decision under the arbitrary and capricious standard.

As best the Court can tell, the question of how to classify the FDA's removal—or addition—of a drug from its shortage list has never been raised or answered. In fact, the regulatory scheme is seemingly silent as to what procedure the FDA must use to make its shortage determinations. Plaintiffs argue that the Delisting Action is a substantive rule under the APA because it "changed the law by establishing a new prohibition." ECF No. 64 at 8. Specifically, Plaintiffs assert that the Delisting Action "creates law by prohibiting all compounding of tirzepatide by Section 503B outsourcing facilities and compounding drugs that are essentially copies of branded tirzepatide products by Section 503A pharmacies" because "there is no difference between" the FDA explicitly declaring "that 'compounding of tirzepatide is prohibited' and removing it from the shortage list." *Id.*

In contrast, the FDA Defendants argue that the Delisting Action is not a substantive rule and was properly issued through adjudication for two reasons. *First*, the FDA simply resolved a factual dispute according to an established statute rather than promulgating a policy-like standard or new interpretation of a statute. *See* ECF No. 83 at 16. And *second*, the FDA has discretion to choose whether to proceed through adjudication or rulemaking because the statutory framework does not explicitly provide what procedure the FDA must use. *See* ECF No. 83 at 16–17.

In reviewing whether an agency action was a rulemaking or an adjudication, courts consider two things. "First, we consider the agency's

characterization of its own action. Second, we must examine the ultimate product of the agency action." *City of Arlington, Tex. v. FCC*, 668 F.3d 229, 240 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013). The Court will first address whether the FDA had the discretion to proceed through adjudication before turning to whether the Delisting Action is in effect an adjudication or substantive rule.

a. The FDA's discretion

When a statutory scheme is silent as to what procedure an agency must use to act, an agency has discretion to proceed through either rulemaking or adjudication. *McDonald v. Watt*, 653 F.2d 1035, 1042 (5th Cir. 1981) ("[T]he Supreme Court held that the decision to make new law through rulemaking or adjudication 'is one that lies primarily in the informed discretion of the administrative agency.'") (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947)). An agency's decision to proceed through rulemaking or adjudication is reviewed under an abuse of discretion standard, and the agency's judgment "is entitled to great weight." *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974); *see also Neustar, Inc. v. Fed. Commc'ns Comm'n*, 857 F.3d 886, 894 (D.C. Cir. 2017) (internal citations omitted) ("[A]s a general matter, '[i]n interpreting and administering its statutory obligations under [an] Act, [an agency] has very broad discretion to decide whether to proceed by adjudication or rulemaking."). Here, the FDA Defendants argue that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication because: (1) Congress requires the shortage list to be "up-to-date" and rulemaking is incompatible with that mandate; (2) engaging in a meaningful notice-and-comment process was not possible given the confidential materials involved; and (3) Congress permits the FDA to withhold confidential information, including the very existence of a shortage. ECF No. 83 at 17–18.[2] Having reviewed the Parties' arguments and the applicable law, the Court finds that the FDA did not

[2]Because the Court finds that the FDA did not abuse its discretion to proceed through adjudication because of the requirement that the list be up-to-date and the issues presented by the confidential data, the Court declines to address the third argument—that the FDA is allowed to withhold information.

abuse its discretion by choosing to proceed through adjudication because notice-and-comment rulemaking is incompatible with Congress's mandate to keep an up-to-date list.[3]

Congress has tasked the FDA with "maintain[ing] an up-to-date list of drugs that are determined by the [FDA] to be in shortage in the United States." 21 U.S.C. § 356e(a). Merriam-Webster defines "up-to-date" as "extending up to the present time: including the latest information." *Up-to-date*, Merriam-Webster's Collegiate Dictionary (11th ed. 2003). If the FDA had chosen to proceed through rulemaking, as Plaintiffs urge, it would have been required by the APA to provide adequate "opportunity to participate in the rule making through submission of written data, views, or arguments. . . ." 5 U.S.C. § 553(c). Generally, for an agency to give adequate opportunity for notice and comment, the APA "requires . . . a minimum thirty-day comment period." *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 779 (5th Cir. 2023). An agency is then required to review the comments, respond to "significant" comments, and make any appropriate changes before officially promulgating a rule. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). Thus, even if the FDA expeditiously participated in notice-and-comment rulemaking, the process would take well over a month. Given the constant fluctuation in national supply and demand numbers for a given drug, a rule based on data that is more than a

[3]Additionally, and in the alternative, the Court finds that the FDA did not abuse its discretion due to the issues presented in achieving meaningful notice and comment while maintaining Lilly's confidentiality. Plaintiffs argue that the Delisting Action is invalid because, *inter alia*, the FDA did not post it in the federal registry for notice and comment before issuing it. However, a simple review of the redacted version of Plaintiffs' Brief in Support of its Motion evidences the difficulty—if not the impossibility—of giving sufficient notice of the data that the FDA relied upon in drafting the proposed "rule," and allowing for meaningful comment on it. *See* ECF No. 66 at 14–19. The redacted data in the above reference section of Plaintiffs' Brief was not even made available to them through the issuance of the Delisting Action. Rather, Plaintiffs were not allowed to see the data until, as a part of this lawsuit, the Court signed and entered an agreed confidentiality agreement. Requiring the FDA to do the same with everyone who wishes to participate in the notice-and-comment process is unattainable and unenforceable.

month old cannot be said to be based on "the latest information" available.

Moreover, the APA "mandate[s] that agencies use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance." *Perez*, 575 U.S. at 101 (internal citation omitted); *Texas v. Biden*, 646 F. Supp. 3d 753, 771 (N.D. Tex. 2022); *Ctr. for Biological Diversity v. Regan*, 691 F. Supp. 3d 1, 8 (D.D.C. 2023). Consequently, if the FDA is required to participate in notice-and-comment rulemaking to remove a drug from its shortage list, then it is required to do the same to add a drug to the shortage list. Requiring the FDA to participate in a lengthy rule-making process to add and remove drugs from the shortage list—based on stale information—cannot be said to be congruent with Congress's mandate for the FDA to maintain an "up-to-date list of drugs . . . in shortage in the United States." 21 U.S.C. § 356e(a)

To emphasize this point, the Court proposes the following scenario. Company A creates a breakthrough drug and is unable to supply enough of the drug to meet an unprecedented national demand. Company A reports its inability to meet demand, as required, and a couple months later the FDA, after going through notice-and-comment rulemaking, places the drug on the shortage list. Company A, understanding the value of its drug, invests tens-of-billions of dollars to ramp up production in order to meet demand. Company A's investment pays off, and it is able to supply enough of the drug to meet the national demand. The FDA, based on the data provided by Company A, engages in notice-and-comment rulemaking, and a couple of months later removes the drug from the shortage list. The day after the rule is final, the demand numbers for the preceding month come in, and due to an unexpected spike, Company A's supply capabilities no longer meet the national demand. Not only did the FDA remove a drug that is in a shortage based on stale information, but it must now once again participate in a lengthy rulemaking process to allow compounders to fill the unmet demand. In contrast, through informal adjudication the FDA can act in a matter of days not months. And while efficiency may not always be the benchmark for agency action, Congress's explicit

command to keep the shortage list up-to-date makes efficiency important here. This example demonstrates why the Court finds that the FDA did not abuse its discretion in choosing to proceed through an informal adjudication rather than notice-and-comment rulemaking.

Based on the foregoing, the Court agrees with the FDA Defendants that the FDA did not abuse its discretion by choosing to proceed through an informal adjudication. However, the label the FDA has attached to the Delisting Action is not dispositive of whether the action should be classified as such. *Safari Club Int'l v. Zinke*, 878 F.3d 316, 332 (D.C. Cir. 2017) ("An agency may not escape the requirements of § 553 by labeling its rule an 'adjudication'"). If the FDA properly exercised its discretion to proceed though adjudication, but the Delisting Action is a substantive rule in effect, then the APA requires that it be subject to notice-and-comment rulemaking. Therefore, the Court now turns to whether the Delisting Action is an adjudication or substantive rule in its effect.

b. Substantive rule or informal adjudication in effect

As a preliminary matter, it appears to the Court that this issue is a "lose-lose scenario" for Plaintiffs. As discussed above, the APA requires the FDA to use the same procedure to add a drug to the shortage list that it uses to remove a drug from the list. Thus, if the FDA's removal of the Lilly Drugs from the shortage list required notice and comment, then so did the FDA's addition of the Lilly Drugs to the list. It is undisputed that Plaintiffs are only able to compound their versions of the Lilly Drugs because of the FDA's placement of the Lilly Drugs on the shortage list. Consequently, if Plaintiffs are correct and the FDA's removal of the Lilly Drugs from the shortage list is invalid because it violated the APA's notice-and-comment requirements, then the FDA's listing of the Lilly Drugs without notice and comment is similarly invalid and Plaintiffs should not have been allowed to compound their versions of the drugs. But, if Plaintiffs are wrong, and the Delisting Action is an adjudication, then both the addition and removal of the Lilly Drugs were proper, and Plaintiffs can no longer compound their versions

of the drugs.[4] Nevertheless, the Court turns to the Parties' arguments regarding whether in effect the Delisting Action is a substantive rule or informal adjudication.

Plaintiffs assert that the Delisting Action is a substantive rule because it created law and is "no different in its force and effect than if Congress had enacted a statute prohibiting" the compounding of tirzepatide. ECF No. 65 at 7–11. Additionally, Plaintiffs argue that the Delisting Action cannot be an adjudication because it does not resolve a factual dispute between two parties, but, rather, is generally applicable to an entire industry. *Id.* The Court will begin with the latter before addressing the former.

i. Broad impact argument

Plaintiffs first argue that the Delisting Action cannot be an adjudication because of its broad impact. While "[a]djudications typically 'resolve disputes among specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals,'" "[i]t is true that an agency need not be presented with a specific dispute between two parties in order to" proceed through adjudication "because § 554 does not limit an agency's use of declaratory rulings to terminating controversies between parties." *City of Arlington, Tex.*, 668 F.3d at 242–43. This is the case because "[j]ust as a class action can encompass the claims of a large group of plaintiffs without thereby becoming a legislative proceeding, an adjudication can affect a large group of individuals without becoming a rulemaking." *Goodman v. F.C.C.*, 182 F.3d 987, 994 (D.C. Cir. 1999) (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 292 (1974) (explaining that an agency may "promulgate a new standard that would govern future conduct" of non-parties in an adjudication)); *see also Neustar, Inc.*, 857 F.3d at 894 ("The fact that an order rendered in an adjudication 'may affect agency policy and have general prospective application,' does not make it rulemaking

[4]Plaintiffs argue that the FDA adding a drug to the shortage list is less legally consequential than removing a drug from the list. The Court finds the opposite to be true. An agency action that suspends statutory exclusivity and allows for a statutorily prohibited action to be temporarily performed is a greater "change" in law than restoring the statutory norms.

subject to APA section 553 notice and comment."); *Nat'l Biodiesel Bd. v. Env't Prot. Agency*, 843 F.3d 1010, 1018 (D.C. Cir. 2016) (internal citation omitted) ("[T]he fact that an agency action applies to a 'large number of [parties]' 'carr[ies] [little] weight' in [the Court's] analysis.").

As pointed out by the FDA Defendants, the FDA routinely conducts adjudications that affect large numbers of third parties: the new drug approval process. *See* 21 U.S.C. §§ 355(d)–(g). The FDA's approval of an NDA triggers numerous effects on potential competitors, such as: (1) prohibiting the FDA from approving a competitor's NDA for any drug containing the same active moiety; and (2) triggering statutory restrictions on compounding drugs that are essentially copies of the approved drug. *Id.* §§ 353b(a)(5), (d)(2)(A); *id.* § 355(c)(3)(E)(ii).[5] The Supreme Court has endorsed the FDA's use of informal adjudications to approve NDAs and remove unsafe drugs from the market, despite those adjudications triggering broad sweeping effects on "several persons or manufacturers." *See, e.g., Weinberger v. Hynson, Westcott & Dunning Inc.*, 412 U.S. 609, 624–26 (1973). Consequently, the Court is unpersuaded by Plaintiffs' broad impact argument.

ii. Creates new law argument

Turning now to Plaintiffs' argument that the Delisting Action is a substantive rule in effect because it creates law, Plaintiffs rely on a series of cases in which an agency listing action was considered a rule.

[5]In their Reply, Plaintiffs attempt to distinguish the FDA's approval of an NDA from an FDA's shortage determination by arguing that an NDA application involves a specific party while a shortage determination does not. *See* ECF No. 98 at 3–4. The Court is unpersuaded by this argument. To approve an NDA, the FDA reviews data submitted by a company and determines whether it satisfies a set of requirements. If the FDA approves an NDA, it triggers statutory exclusivity for the submitting company as well as a statutory prohibition against compounding the drug. Similarly, to make a shortage determination, addition or removal, the FDA reviews data submitted by a company to determine whether supply is greater than demand over a period of time. If, for example, the FDA finds that a shortage no longer exists, it reinstates the same statutory exclusivity and prohibitions that the FDA's approval of that drug's NDA put into place. And those statutory provisions apply to the same company and compounders that were affected by the NDA adjudication. Thus, Plaintiffs argument that one affects specific parties and the other does not, is unpersuasive.

ECF No. 65 at 8–10. Of the cases cited by Plaintiffs, they rely most heavily on *Safari Club*. 878 F.3d 316. Because that case is demonstrative and dispositive of Plaintiffs' other cited authorities, the Court will focus its analysis on *Safari Club*.

The "basic distinction between" an adjudication and rulemaking is that adjudications are "proceedings designed to adjudicate disputed facts in particular cases," whereas rulemakings are "proceedings for the purpose of promulgating policy-type rules or standards." *See United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 244–45 (1973); *see also* 5 U.S.C. §§ 551(4) (defining "rule"), 551(6) ("order"), 551(7) ("adjudication"). The "line between" adjudication and rulemaking "is frequently a thin one. . . ." *Gen. Am. Transp. Corp. v. Interstate Com. Comm'n*, 883 F.2d 1029, 1030 n.2 (D.C. Cir. 1989). While it can be difficult to decipher where courts draw the thin line between adjudication and rulemaking, courts generally find that an agency action is an adjudication when it involves "concrete and narrow questions of law the resolutions of which would have an immediate and determinable impact on specific factual scenarios." *City of Arlington, Tex.*, 668 F.3d at 243. Rulemaking, on the other hand, is identifiable when the application of the action "will only become clear after adjudication of the dispute in a court of competent jurisdiction." *Id.*

This distinction can be seen in *Safari Club*. In *Safari Club*, the United States Fish and Wildlife Service (hereinafter the "Service") issued findings providing that it lacked sufficient information to make a positive finding that the sport-hunting of elephants would enhance the survival of the species. 878 F.3d at 323. The Service's findings also "temporarily banned imports of sport-hunted trophies of elephants." *Id.* The plaintiffs filed a lawsuit challenging the findings and argued, *inter alia*, that the findings were substantive rules despite the Service's insistence that they were adjudications. *Id.* at 331–34. The United States Court of Appeals for the District of Columbia agreed and held that the Service's findings could not be adjudications because, unlike the denial of "an application for an import permit," they had "no immediate legal consequences for any specific parties." *Id.* at 334–35. Rather, the D.C. Circuit held that the findings were substantive rules because they

"established a standard binding on the agency . . . to be applied to future requests" and were "only meant to bind hunters in future permitting adjudications and enforcement actions." *Id.* at 334.

Applying the principle that "adjudications immediately bind parties" while rules have "only future effect" to this case, the Court finds that the Delisting Action is an adjudication for two reasons. *First*, the Delisting Action undoubtably has immediate legal consequences for specific parties. The immediate consequences of the Lilly Drugs being removed from the shortage list are, *inter alia*, that Lilly regains its statutory exclusivity over tirzepatide products, and that 503A and 503B Compounders, like Plaintiffs, must cease production of their versions of the drugs. Plaintiffs seemingly concede the immediate effect the Delisting Action has on them as they argue that the removal of the Lilly Drugs from the shortage list will force their tirzepatide products "off the market," causing them irreparable harm. ECF No. 65 at 2, 23. In contrast, the Service's findings in *Safari Club*, did not cancel any prior but unfulfilled importation approvals, they only served to govern the Service's consideration of future applications. *See Safari Club*, 878 F.3d at 333 ("[T]he Service's ban on imports was only meant to bind hunters in future permitting adjudications and enforcement actions . . . ."). Thus, unlike *Safari Club*, where the findings had no immediate impact on a specific party, the Delisting Action triggered statutory provisions, immediately restoring Lilly's exclusivity and requiring compounders to stop compounding tirzepatide.

And *second*, the Delisting Action does not promulgate a new policy-type rule or standard that will govern the FDA's future actions. Instead, it made a specific factual determination based on the statutory definition of shortage. The Delisting Action did not change or interpret the statutory definition of shortage. It simply fulfilled the FDA's mandate to determine whether tirzepatide products are in shortage. Put another way, unlike *Safari Club*, where the Service's findings "implement[ed] and interpret[ed] [a rule's] enhancement requirement" to make a policy like judgment about what level of protection elephants needed to be afforded to enhance their chance of survival; the FDA's Delisting Action simply looked at the evidence presented and made a

factual determination on whether one number was bigger than another. 878 F.3d at 334 (internal quotations omitted). While it is true that the FDA's numerical determination had the immediate effect of prohibiting Plaintiffs from continuing to compound tirzepatide products, that prohibition did not come by way of a new agency interpretation, but rather by operation of an existing statute.

This distinction is further evidenced by the difference in the prospective effect of the respective agency actions. In *Safari Club*, the Service's findings determined that a ban on the future importation of elephant parts was appropriate until further notice to protect the species. This new standard served as a guide for the Service's consideration of future importation applications. In contrast, rather than creating a standard by which the FDA will consider future compounding applications,[6] the Delisting Action immediately reinstated, as discussed above, statutory protections and prohibitions. In fact, the Delisting Action provides no guidance for any future shortage determination the FDA must make, as every shortage determination—even potentially one involving tirzepatide—must be made on a case-by-case basis. Such case-by-case factual determinations have been found by courts to be adjudications. *See, e.g., Vanda Pharms., Inc. v. FDA*, 436 F. Supp. 3d 256, 270 n.4 (D.D.C. 2020) (rejecting the argument that the FDA's analysis of scientific literature in an adjudication applied to future cases such that it was a legislative rule, and noting that, unlike in *Safari Club*, the agency's analysis was "in the context of 'adjudicating a particular set of disputed facts'").

The FDA's Delisting Action made a factual determination about whether from [redacted] to [redacted], and projecting forward through [redacted], the supply of the Lilly Drugs was equal to or greater than the demand. It did not make a policy-like determination. Therefore, the Court finds that the Delisting Action was an informal adjudication—not a rule. And as a result, the FDA was not required to submit the Delisting Action to notice and comment or publish it in the

[6]In fact, the statutory exclusivity that Lilly immediately regained upon the issuance of the Delisting Action explicitly prohibits the FDA from even considering an application. 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii).

Federal Registry. Accordingly, Plaintiffs are unlikely to succeed on their notice-and-comment and failure to publish claims.

2. Arbitrary and Capricious Claims

The Court now turns to whether Plaintiffs demonstrate a likelihood of success on the merits because the FDA's actions were arbitrary and capricious. Agency decisions are "presumptively valid; the [plaintiff] bears the burden of showing otherwise." *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024); *Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 120 F.4th 494, 504 (5th Cir. 2024) (citing *Medina Cnty. Env't Action Ass'n v. Surface Transp. Bd.*, 602 F.3d 687, 699 (5th Cir. 2010). "If the agency articulates a rational relationship between the facts found and the choice made it does not act arbitrarily or capriciously." *Joseph v. Dir. of Texas Serv. Ctr., U.S. Citizenship & Immigr. Servs.*, No. 24-40249, 2025 WL 458001, at *3 (5th Cir. Feb. 11, 2025) (internal quotation and citation omitted). The "focal point" of that review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). And "[j]udicial review under that standard is deferential, a[s] a court may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While courts "may not supply a reasoned basis for the agency's action that the agency itself has not given," courts are to "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Tex. Med. Ass'n,* 120 F.4th at 504 (citing *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983) (quotations omitted)).

Here, Plaintiffs assert that the Delisting Action is arbitrary and capricious because: (1) it does not sufficiently identify or analyze the key parameters of the shortage determination; (2) it is facially incoherent and inconsistent; and (3) it improperly ignored countervailing evidence. *See* ECF No. 68 at 19–22; *see also* ECF No. 65 at 13–23. The Court will address each in turn.

a. Identification of key parameters[7]

Plaintiffs first argue that the Delisting Action is arbitrary and capricious because it fails to identify what time period the FDA looked at to make its shortage determination. ECF No. 68 at 19–20; ECF No. 65 at 14–19. Plaintiffs assert that the Delisting Action's failure to state a specific time frame is fatal because it is inconsistent with the statutory language and it "blinded [the] FDA to Lilly's inconsistent temporal presentations that concealed shortages." ECF No. 65 at 14. The Court need not spill much ink on this argument as it plainly fails.

Even assuming without deciding that the FDA was required to explicitly provide what period of time on which it based its shortage determination, the FDA satisfied that burden. On multiple occasions, the Delisting Action clarifies that it considered the previously produced supply and demand numbers for [redacted] to [redacted], as well as the recently released [redacted] numbers and the projected numbers through [redacted]. *See* ECF No. 65-1 at 1, 7, 8, 9, 10, 14, 15. This time period was seemingly evident to Plaintiffs as, in the same section of their brief, they take issue with the specific period of time used and argue that the Delisting Action is arbitrary because it failed to consider evidence from outside that time period. ECF No. 65 at 15–16 (asserting that the FDA erred because it did not consider past deficits or surplusages in its analysis as it started [redacted]" and looked at the numbers through [redacted]). Thus, in one breath, Plaintiffs assert that the FDA failed to identify a specific time frame and in another that the FDA's time frame was erroneous. While the Delisting Action occasionally references narrower time frames, the decision as a whole focuses on a set of data and projected data from a specific time frame—[redacted] to [redacted].

Thus, the Court finds that the FDA sufficiently identified what time period it considered in making the shortage determination. Further, the Court finds that because it is tasked to determine whether a shortage

[7]The Court does its best to separate out Plaintiffs' first two arbitrary and capricious claims as they intermingle them in their brief. *See* ECF No. 65 at 14–19.

exists over a specific period of time, the FDA did not err in failing to consider evidence from outside that time frame. Therefore, the Court finds that Plaintiffs have failed to demonstrate a likelihood of success on the merits of this claim.

b. Facially incoherent and inconsistent

Before turning its attention to Plaintiffs arguments for why the Delisting Action is facially incoherent and inconsistent, the Court finds it prudent to begin by briefly summarizing the FDA's decision.

i. Summary of the Delisting Action

The Delisting Action concluded that the tirzepatide shortage was over because the data demonstrated "that Lilly's supply is currently meeting or exceeding demand for these drug products, and that Lilly has developed reserves that it now holds in its finished product inventory, plus significant units of semi-finished product." ECF No. 65-1 at 1. Additionally, the FDA noted that Lilly received approval to produce doses in vials, and that it has scheduled substantial additional production over the coming months. *Id.* [redacted]

In making its determination, the FDA reviewed:

> [D]etailed information and data regarding its production and inventory of these drug products at various points in time, including stock reports that show quantities supplied and demanded, and inventory held in stock, for all strengths of these drug products; cumulative quantities supplied to and demanded by its customers in the year 2024; projected demand and supply in future months; and wholesaler inventory data, among other information.

Id.[8]

The data reviewed by the FDA is best summarized by two tables contained within the Delisting Action, as shown below:

[8]"[A]mong other information" includes numerous information submitted by Plaintiffs and others to demonstrate the existence of a shortage. Because that is the basis for Plaintiffs' third arbitrary and capricious claim, the Court does not discuss that information in this section.

Table 4. Lilly-reported cumulative demand and cumulative supply of tirzepatide single-dose pens for [redacted] (thousands of doses)[31]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Table 6. Lilly-reported projected cumulative demand and cumulative supply of tirzepatide single-dose pens [redacted] (thousands of doses)[58]

Cum. demand	[redacted]
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Cum. supply	
2.5	
5	
7.5	
10	
12.5	
15	
Total	
Net (cum. supply – cum. demand)	
2.5	
5	
7.5	
10	
12.5	
15	
Total	

Id. at 10, 15.

These tables summarize Lilly's reported and projected supply and demand numbers beginning in [redacted] and concluding in [redacted]. The tables are constructed in a cumulative fashion with each month building on the previous month(s). This means that each month's column shows the total supply and demand numbers from [redacted] to the specified month. As a consequence, the numbers for [redacted] appear astronomically larger than those for [redacted].

The FDA determined that the shortage had concluded based on the fact that: (1) from [redacted] to [redacted], Lilly's total supply

([redacted]) outpaced total demand ([redacted]); (2) at least through [redacted], the shortage would not return based on the projections that Lilly's total supply ([redacted]) would continue to outpace total demand [redacted]; and (3) the information provided by wholesalers "further indicate[d] that nationwide supply for [Lilly's] products is exceeding demand." ECF No. 65-1 at 10–15. Furthermore, the FDA noted that its determination was bolstered by: (1) the months-long production of data by Lilly to the FDA; (2) Lilly's supply of over [redacted] units of semi-finished syringe products (products that have already completed sterile manufacturing and are awaiting labeling and packaging); (3) the recent approval of Lilly's vial versions of the drugs, which allows Lilly to supply more product than currently projected; and (4) Lilly's investment into additional production facilities that will soon be in operation. *Id.* After reviewing the other evidence provided by Plaintiffs, and others, the FDA determined that the nationwide shortage had ended and reaffirmed its decision to remove the Lilly Drugs from the shortage list. *Id.* at 16–23.

ii. Plaintiffs' arguments

Plaintiffs seemingly insist that the Delisting Action needed to be perfect. It did not. Rather, it needed only to "articulate[] a rational relationship between the facts found and the choice made." *Joseph*, 2025 WL 458001, at *3. Thus, the Court need not confuse the trees for the leaves. The question before the FDA was, for "a period of time" did "the demand or projected demand for the [Lilly] drug[s] within the United States exceed the supply of the [Lilly] drug[s]." 21 U.S.C. § 356c(h)(2). The FDA answered that question in the negative and therefore found that the shortage had ended. Consequently, the question before the Court is whether the FDA's decision, that supply of the Lilly drugs outpaced demand for a period of time, was reasonable in light of the evidence before it. For the reasons set out *infra*, the Court answers that question in the affirmative.

The crux of Plaintiffs' argument that the Delisting Action is incoherent and inconsistent is that "Lilly's use of cumulative figures misled or at least confused [the] FDA." ECF No. 65 at 15. Plaintiffs claim that this confusion obfuscated the fact that the shortage still persists

and created an unreasonable reliance on Lilly's statements. *Id.* at 15–19. Specifically, Plaintiffs argue that the Delisting Action is facially incoherent and inconsistent because: (1) the FDA looked at the total supply and demand data for the relevant period rather than at "monthly snapshots;" (2) the FDA [redacted], but then did not [redacted]; (3) the "FDA made no finding of demand under any consistently defined time period" as "[o]nly cumulative tables report demand, and each month has a different baseline;" and (4) the Delisting Action "turns on" Lilly's unsupported statement that it can supply over [redacted] a month. *Id.*

Plaintiffs' first argument, that the Delisting Action should not have considered cumulative data, fails. It is axiomatic that to consider something for a period of time requires considering it for the entire period of time. Yet, Plaintiffs argue that the FDA's decision is without reason because there were data points from shorter periods of time, within the overall time frame, that could lead to a different result. The real and "detailed data" considered by the FDA shows that for the period of [redacted] to [redacted], Lilly supplied some [redacted] more than were demanded ([redacted] supplied - [redacted] demanded). The FDA, relying on projected data,[9] found that for the period of [redacted] to [redacted], Lilly would be capable of supplying at least [redacted] more than would be demanded [redacted] supplied - [redacted] demanded).

Plaintiffs insist that the FDA should have considered the data on a month-to-month basis, rather than through cumulative numbers, and point out that there was more demand than supply produced for individual months. However, this argument ignores the fact that even if

[9]There is no evidence to show that the FDA's reliance on the projections was unreasonable as they provided that Lilly's [redacted] " ECF No. 65-1 at 14. Further, [redacted]

the charts were based on each individual month's numbers, the FDA would have had to add them together to get the total numbers for the relevant period of time. Thus, the result would have been the same as surplus carries over[10] and every month ([redacted]–[redacted] ended with a net total surplus. *See* ECF No. 65-1 at 10, 15. Consequently, Plaintiffs are unlikely to succeed on the basis that the FDA fatally erred by considering cumulative numbers.

Plaintiffs next argue that the Delisting Action is arbitrary because the FDA [redacted]. In addition, Plaintiffs argue that the FDA erred by [redacted]. Plaintiffs claim that the FDA had no reason to [redacted], because doing so ignores the fact that surpluses/shortages carry over. While true, it ignores the fact that a period of time requires a starting and ending point. Thus, it was not unreasonable for the FDA to [redacted], as it was the beginning of the relevant time period.[11] Additionally, for the same reason Plaintiffs' cumulative numbers argument fails so does their assertion that the FDA should have [redacted]. In evaluating data for a period of time, one looks at the whole not just part. Therefore, Plaintiffs are unlikely to succeed on the basis that the FDA arbitrarily started [redacted], and [redacted].

Plaintiffs third argument, that the FDA "made no finding of demand under any consistently defined time period" fails for the same reasons. The FDA considered total demand for the relevant time period based on actual and projected data. The argument that the cumulative demand numbers were based on different lengths of time ignores the fact that the supply numbers were based on the same lengths of time. Additionally, just as above, even if they were broken down by month, the FDA would have still been required to total the months up to

[10]Each dose can be stored for up to 24 months. ECF No. 90 at 12.

[11]Plaintiffs do not, and cannot, argue that the FDA was required to look at numbers all the way back to the approval of the Lilly drugs. As Plaintiffs do argue, the FDA was required to choose a time period for its analysis. The FDA did and it looked at the actual and projected numbers for that time frame. The statute does not require more of the FDA and neither does this Court.

evaluate if the total demand outpaced total supply for the time period being considered. Thus, Plaintiffs are unlikely to prevail on their demand calculation argument.

Finally, Plaintiffs assert that the Delisting Action is arbitrary because it "turns on" Lilly's unsupported representation that it can now supply over [redacted] a month. This argument also fails. Even assuming without deciding that Lilly's [redacted] a month estimate is unsupportable, Plaintiffs cannot show that the FDA's determination has no reasonable relationship to the facts presented for two reasons. *First*, Plaintiffs statement is a mischaracterization, as the FDA considered significantly more information than Lilly's explicit [redacted] estimate. *See* ECF No. 35-1 at 1. And *second*, even if the monthly estimate is unsupportable by the data, that does not negate the fact that the actual numbers show that total supply outpaced demand for the relevant period. *Id.* at 10, 15. Thus, even if the FDA was never presented with Lilly's estimate, the actual supply and demand numbers provide the FDA with a reasonable basis for determining that the Lilly Drugs are no longer in shortage. Accordingly, because the FDA was not required to be perfect, Plaintiffs are unlikely to succeed on their claim that the Delisting Action is incoherent and inconsistent.

c. Countervailing evidence

Finally, Plaintiffs assert that the Delisting Action "arbitrarily waved away all evidence of shortage." ECF No. 65 at 19–23. Specifically, Plaintiffs claim that the FDA reviewed all of the evidence provided by them, and others, with "hyper-skepticism."[12] *Id.* Plaintiffs, and others, provided four categories of evidence to the FDA: (1) screenshots of pharmacy wholesalers websites; (2) patient reports; (3) news reports; and (4) compounding numbers. *Id.* Plaintiffs argue that all of this evidence shows that the FDA unreasonably relied on Lilly's assertions and should not have been waved away. *Id.* The Court will address each

[12]As a preliminary matter, the Court notes that the FDA also scrutinized and rejected some of Lilly's evidence based on the same standards it applied to the countervailing evidence. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53. If nothing else, this shows that the FDA did not blindly rely on Lilly's assertions and evidence.

set of evidence to determine if the FDA's finding that it did not outweigh or undermine the evidence provided by Lilly was reasonable in light of the facts before it.

First, Plaintiffs point to the screenshots of wholesalers' webpages showing that on certain days some tirzepatide products were unavailable. *Id.* at 19–20. The FDA reviewed the screenshots and found that the evidence did not "undermine[] or outweigh[] the information provided by Lilly . . . with respect to availability of product to wholesalers and retailers" because: (1) Lilly provided data from the wholesalers showing that Lilly is meeting or exceeding wholesaler demand for the Lilly Drugs; (2) of supply chain dynamics; (3) most of the screenshots were undated; (4) Lilly [redacted] and (5) some localized and temporary supply issues do not demonstrate a national shortage. ECF No. 65-1 at 19–21.

Plaintiffs take issue with all of the FDA's explanations, but most notably argue that "[d]elay in shipping of the drug" is a statutory indicator of a shortage. ECF No. 65 at 20 (citing 21 U.S.C. § 356e(b)(3)(F)). While a significant delay in shipping could affect supply on a national level, it was reasonable for the FDA to conclude that a "[redacted]" delay for a specific dose of tirzepatide on a specific retailer's website does not rise to the level of a national shortage. Similarly, the Court finds that the FDA's review and explanation of the data related to screenshots of wholesalers' websites was not unreasonable in light of the additional data provided and supply chain dynamics.

Second, Plaintiffs claim that the FDA unreasonably found that Lilly's evidence was not outweighed by the "tens of thousands" of "reports of patients" not being able to obtain tirzepatide. ECF No. 65 at 20. Plaintiffs, and others, submitted website "survey data" where people responded in the affirmative to a question asking if they have had "an inability to access name brand GLP-1s." *Id.* at 20; ECF No 65-1 at 17. The FDA reviewed the submissions and found that they did not undermine Lilly's evidence that the shortage was over because: (1) there is no way to verify how many individuals actually filled out the reports,

when they filled out the reports, or when their inability to obtain the drugs occurred; (2) the prompt does not define "inability to access" so some may be reporting that a pharmacy was out of stock and others that their doctor did not prescribe them the medication; (3) of business decisions made by pharmacies as well as their limited storage capacities; and (4) some localized and temporary supply issues do not demonstrate a national shortage. ECF No 65-1 at 16–19. Given the issues with the evidence as articulated by the FDA, the Court finds that the FDA did not unreasonably determine that Lilly's evidence is not outweighed by the patient survey reports.[13]

Third, Plaintiffs assert that the FDA "ignored" news coverage of the shortage situation. ECF No. 65 at 21. With regard to this evidence, the FDA stated:

> FDA reviewed various articles and blog posts submitted by various groups, as well as other news coverage. While these pieces discussed various aspects of the shortage situation, FDA did not find them to contain probative evidence relevant to the analysis FDA must conduct to determine whether a shortage has resolved. While some of these sources contained personal accounts of inability to get a particular product at a particular time, like the evidence discussed in sections II.B.1.i and ii above, those individual accounts do not undermine or outweigh the more specific, reliable, comprehensive, and current information that has been provided by Lilly demonstrating its ability to supply enough product to meet demand.

ECF No. 65-1 at 21.

The Court finds that it was not unreasonable for the FDA to give more weight to specific, reliable, comprehensive, and current information from Lilly, than news reports and blog posts from sources who may have had ulterior motives and lacked the same detailed data presented to the FDA. Consequently, the Court finds that the FDA did not arbitrarily wave away the news coverage of the shortage situation.

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[13]As previously noted, the FDA found some of Lilly's evidence to be unpersuasive [redacted]. *See, e.g.*, ECF No. 65-1 at 13 n.44., 13–14 n.53.

Fourth, and finally, Plaintiffs argue that the "FDA erred" by "disregarding the '[] sales volume of compounded tirzepatide' as evidence of demand." ECF No. 65 at 21–23. Specifically, Plaintiffs claim that FDA "erroneously deemed compounded products irrelevant," "disregard[ed] demand for compounded products because they beat Lilly's on price," failed to take into account the correct volume of compounding, and incorrectly assumed that some patients were using compounded tirzepatide for off-label uses. *Id.*

Plaintiffs' first point, that the FDA deemed compounded products irrelevant, fails. The FDA stated that the number of compounded products has "minimal relevance" on the current demand of the Lilly Drugs, but that it is relevant to projected demand—after the compounded drugs are removed from the market. ECF No. 65-1 at 22–23. On that basis, the FDA considered whether Lilly would be able to fill the demand hole that would be left after the compounded drugs were removed. *Id.* at 23–28. After a lengthy discussion, the FDA found that based on the projections Lilly would be able to meet the projected demand. *Id.*

Plaintiffs' second and fourth arguments similarly fail. In essence, Plaintiffs take issue with the FDA's statements that demand for compounded drugs does not translate one-for-one to demand for the Lilly Drugs because of price considerations and patients' current off-label use. ECF No. 65 at 21–23. Lilly did not zero out the projections of demand based on these principles, it simply found these were factors to consider in projecting the demand of the Lilly Drugs. ECF No. 65-1 at 26–27. It is not unreasonable to consider missuses or price differences in attempting to calculate a projected national demand.

Finally, Plaintiffs assert that the FDA improperly evaluated how much compounding was occurring. ECF No. 65 at 22. Plaintiffs claim that the FDA erred in considering only the "first six months of 2024" while considering [redacted] for Lilly's data. But the data from the first six months of 2024, was "the most recent complete reporting period" that was available to them. ECF No. 65-1 at 24–25. Plaintiffs also assert that the FDA overcalculated how much Plaintiffs were producing. ECF No. 65 at 22. Even if true, this does not show error as the FDA conducted its

analysis based on inflated compounding numbers, which would only have helped Plaintiffs' position on the shortage. Lastly, Plaintiffs argue that the FDA should have investigated more based on the evidence provided that thirty-seven pharmacies produced roughly 500,000 doses per month. ECF No. 65 at 22. The FDA considered this evidence and found that "[e]ven assuming that all of these doses have been supplied to the market and, upon the curtailing of compounding, would translate to demand for Lilly's products, this would represent a very small amount relative to Lilly's production and inventory." ECF No. 65-1 at 24. Furthermore, the FDA had no obligation "to conduct or commission [its] own empirical or statistical studies." *Prometheus Radio Project*, 592 U.S. at 427. Accordingly, the Court finds that the FDA's treatment of the evidence submitted by Plaintiffs, and others, was reasonable based on the evidence it had before it. *Id.* Thus, Plaintiffs are not likely to succeed on this claim.

B. Irreparable Injury

Parties frequently confuse the magnitude of a harm with the irreparability of a harm. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 18–20 (2008); *Rest. Law Ctr. v. U.S. Dep't of Lab.*, 66 F.4th 593, 597 (5th Cir. 2023) (citing *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016) ("In determining whether costs are irreparable, the key inquiry is 'not so much the magnitude but the irreparability.'")). Yet even enormous harms can be compensable by money damages, thus failing to justify injunctive relief. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("The key word in this consideration is irreparable. Mere injuries, however substantial . . . are not enough. The possibility that adequate compensatory or other relief will be available at a later date . . . weighs heavily against a claim of irreparable harm.") (internal quotations omitted). That's off the table here, as Plaintiffs sue the federal government and cannot recover monetary compensation. *See Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1136 (5th Cir. 2021). And "complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Louisiana v. Biden*, 55 F.4th 1017, 1034 (5th Cir. 2022) (internal citation omitted); *see generally Rest. Law Ctr.*, 66 F.4th at 433. Here, without a

preliminary injunction, Plaintiffs will suffer unrecoverable financial losses, which constitutes irreparable harm.[14] *White Lion Invs., LLC*, 16 F.4th at 1136.

C. Public and Private Interests

Finally, Plaintiffs must show that, if the injunction is denied, the threatened injury outweighs any harm that will result if the injunction is granted, and that the granting of an injunction will not disserve the public interest. *See Mock v. Garland*, 75 F.4th 563, 577 (2023). These factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). On one hand, if the Department is enjoined, it "suffers the irreparable harm of denying the public interest in enforcement of its laws." *Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017). On the other, "it is always in the public interest" to stop enforcement of unconstitutional or invalid laws. *See Jackson Women's Health Org. v. Currier*, 760 F.3d 448, 458 n.9 (5th Cir. 2014) (internal citations omitted). The Parties' arguments for both interests are the same.

Plaintiffs argue that if the Court denies an injunction, patients will be deprived of their medications. ECF No. 65 at 24. In contrast, the FDA Defendants claim that if the Court grants an injunction, patients will continue to be subject to dangerous compounded versions. ECF Nos. 83 at 24; 90 at 22–25. Congress considered both of these interests in crafting the relevant regulatory scheme. As discussed above, compounding is generally prohibited due to the reduced oversight and the potential harms associated with the practice. However, Congress chose to allow for compounding when a drug is on the FDA's shortage list so that patients can receive their medications. If Congress thought it prudent to account for both of the asserted public interests at issue here, it is not for this Court to make a policy determination on which is

[14]Lilly argues that Plaintiffs are compounding in violation of the relevant statutes. However, the FDA does not contest this element. The Court agrees with Plaintiffs that this argument has no place in this case and must be decided, if at all, in a different lawsuit. Thus, for the purposes of this Motion, the Court does not consider that argument.

greater.[15] Thus, the Court finds that the public and private interests at issue in this case are a wash and do not weig in favor of or against the granting of an injunction.

CONCLUSION

For the reasons set out above, Plaintiffs' Motion for Preliminary Injunction and Stay is **DENIED.**

Given the agreed confidentiality agreement that was entered into by the Parties, and enforced by the Court, the undersigned finds it appropriate to file this unredacted opinion under seal. Shortly after the opinion is filed, the Parties will be provided, via email, an unsigned PDF version of the order. It is **ORDERED** that, **on or before 4:00 p.m., March 7, 2025**, the Parties shall submit, via response to the email, an agreed upon version of the order containing any appropriate redactions. After receiving and reviewing the Parties' version, the Court will issue the redacted order.

SO ORDERED on this **5th day of March 2025.**

Mark T. Pittman

MARK T. PITTMAN
UNITED STATES DISTRICT JUDGE

[15]The Court agrees with John Adams's sentiment that the judiciary should avoid exercising the powers of the legislative and executive branches, so that this Nation may remain "a government of laws and not men." Mass. Const. art. 30; *John Adams, Architect of American Government*, https://www.mass.gov/guides/john-adams-architect-of-american-government.